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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,201	04/22/2004	Daniel J. Drucker	016777-0616	5544

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
02/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,201	DRUCKER ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 6-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 09 July 2008 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/829,201 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 09 July 2008 is acknowledged and entered. Following the amendment, claims 3 and 5 are canceled, and claims 1 and 6 are amended.

Currently, claims 1 and 6-11 are pending, and claims 1 and 6 are under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 3 and 5 are moot as the applicant has canceled the claims.

The lack of written description rejection of claims 1 and 6 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

Formal Matters:

Claims

Claim 1 is objected to for the following informalities, appropriate correction is required for each item:

Claim 1 recites "a medical condition, disorder or disease *resulting* from ...". "A medical condition, disorder or disease resulted from ..." is suggested.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly amended claim 1 is indefinite for the recitation "a medical condition, disorder or disease resulting from elevated nutrient intake" because it is unclear what the term "elevated nutrient intake", and how it is measured, and it is unclear what diseases are encompassed by the limitation. Further, the specification does not define the term. The metes and bounds of the claim, therefore, cannot be determined.

The remaining claim is included in this rejection because it is dependent from the specifically mentioned claim without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claim 1 recites the limitation "a medical condition, disorder or disease resulting from elevated nutrient intake". While the specification teaches that subjects standing to benefit particularly from this pharmaceutical combination therapy are those suffering from conditions and disorders that result from *persistently and inappropriately* elevated nutrient intake or patients with body weight control disorders, including subjects suffering from obesity (page 19, [0049]), it does not provide sufficient support for a condition resulted from just any elevated nutrient intake ("occasional", for example, in diseases such as acute pancreatitis), which constitutes a broader scope than that of "persistently and inappropriately elevated nutrient intake". Therefore, the amendment has changed the scope of the invention, and is not supported by the original disclosure.

This is a new matter rejection.

Claims 1 and 6 also remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a pharmaceutical composition comprising Gly_2GLP-2 and exendin(9-39), and a kit thereof, for the use of reducing or inhibiting food intake or suppressing appetite in mice by intracerebroventricular injection or central administration, does not reasonably provide enablement for claims to said pharmaceutical composition for the use of treating medical condition, disorder or disease resulting from elevated nutrient intake or any/all types of body weight control disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims, for the reasons of record set forth in the previous Office Actions mailed on 4/10/07 and 1/9/08, and for the reasons below.

Applicants argument filed on 09 July 2008 has been fully considered, but is not deemed persuasive for the reasons below.

At page 4 of the response, the applicant argues that only some of the Wands factors were discussed by the Examiner in the rejection, contrary to MPEP, which states that "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others, the examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole". This argument is not persuasive because, while the rejection based on an analysis of only one of the Wands factors is improper, MPEP does not require that the rejection has to meet all the factors, and the examiner has considered all the evidence related to each of these factors, and any conclusion of nonenablement is based on the evidence as a whole (more below). Applicants further argue that the breadth of the pending claims has been reduced, both in the pharmaceutical combinations claimed, and in their prospective uses, and that the invention is pharmaceutical in nature, and is supported by animal studies such as the study of intracerebroventricular peptide injections on food intake in mice, thus, these first two Wands factors favor patentability of the pending claims. This argument is not persuasive because, while the breadth of the composition has been reduced, the breadth of the prospective uses has been

broadened, i.e., it encompasses any or all conditions/diseases resulted from "elevated nutrient intake or patients with body weight control disorders" (whatever it means), as opposed to treating a condition/disease "for which treatment with GLP-2 is indicated" (the original claim 1). There is no evidence that said composition can be used for any or all conditions/diseases resulted from "elevated nutrient intake or patients with body weight control disorders". For example, anorexia would be qualified as a "body weight control disorder", and it is the opposite of obesity. As addressed in the last Office Action, the present specification merely teaches said composition suppresses appetite and thereby reduces food intake (for treating obesity). Therefore, it is obvious that the claimed pharmaceutical combination would not be suitable for treating the encompassed conditions such as anorexia. Further, with respect to the second factor, the nature of the invention, it is very complex and unpredictable, which is indicated by the prior art, as addressed in the previous Office Actions.

Applicants further argue, on page 4 of the response, that the specification (paragraph [0051]) addresses differential results in rat, mouse and human models, and expects a differential result in rats and humans and proposes solutions for addressing the issue, and that the art cited by the Examiner supports a finding that the level of one of ordinary skill in the art (the next Wands factor) had risen from the time of publication of the Tang-Christensen article in 2000 and the filing of the present application, and shows that one of ordinary skill had greater understanding of the models involved at the time of filing of the present application, thus increasing the predictability in the art. This argument is not persuasive because, while one of ordinary skill in the art might have a better understanding of the models involved (i.e., they vary a great deal), the very fact of the contradictory results from the different animal models (even the same species (rat vs. mouse), and/or different administration routes is a clear indication of the unpredictable nature in this field. Further, the specification teaches the effect of the composition on food intake in mice when administered by intracerebroventricular peptide injections, which would not be suitable for treating human or animals other than experimental mice. Therefore, contrary to applicants argument, the data clearly demonstrates that undue experimentation would be required prior to using the claimed pharmaceutical combination for said intended use. With respect to paragraph [0051], it is irrelevant because it recites a subtle as "Embodiments of the invention and methodologies useful in the practice thereof are now described in the following examples".

At page 5 of the response, the applicant argues, regarding the remaining Wands factors, that the inventors provide ample support for formulations of Gly_2GLP-2 and exendin (9-39), and data from mouse models as to its use and how to carry the effect of induced anorexia into human and other species, and that Applicants also provide teachings as to how methods and combinations according to the present invention may be adapted for use in different species, dosing considerations, and discussion of various formulation types and routes. This argument is not persuasive because, while the specification demonstrates intracerebroventricular administration of the compositions for inhibiting food intake in mice, it does not provide any evidence as to treating humans or any other animals. Given the fact, as addressed in the previous Office Actions, that when the GLP-1 receptor antagonist, exendin(9-39), is used with GLP-2 centrally, it has completely different effects on GLP-2-induced anorexia in mice and rats, there is no way that one skilled in the art would be able to predict the effect on humans without undue experimentation. Furthermore, as addressed previously and above, intracerebroventricular administration of drugs for inhibiting food intake (as demonstrated in the present specification) would not be a practical treatment method in humans or other species, and the specification has not shown any other way of administration that would be as effective. Clearly, undue experimentation would be required of the skilled artisan prior to using the claimed invention in its full scope.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
8/28/08